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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,697	11/16/2001	Robert Cosmo Di Luccio	14,853	2942
23556	7590	02/04/2005	EXAMINER	
KIMBERLY-CLARK WORLDWIDE, INC. 401 NORTH LAKE STREET NEENAH, WI 54956			REICHLER, KARIN M	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/990,697	Applicant(s) DI LUCCIO ET AL <i>DL</i>	
	Examiner Karin M. Reichle	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004 and 12 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-22 and 44-77 is/are pending in the application.
- 4a) Of the above claim(s) 44, 47-51 and 54-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-22, 45-46 and 52-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8-18-03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction requirement set forth in Paper No. 5 is still deemed proper and made FINAL.

2. Applicant's election without traverse of Group I and the species of the product made by the process using a valve jet in the reply filed on 7-28-04 and 11-18-04 is acknowledged.

The restriction/election requirement set forth in the 6-25-04 Office Action is still deemed proper and made FINAL.

3. Claims 44, 47-51 and 54-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7-28-04 and 11-18-04.

Claims 47-51 are no longer deemed generic because, upon further perusal of the specification as originally filed, while it is disclosed the medicament, i.e. an element used to manufacture the claimed article, has the claimed melting points and shear viscosities, it is not disclosed what the melting points and viscosities of the discrete segments of the end product made by the process of using a valve jet are. The Examiner apologizes for the prior inclusion of such claims in the group of claims considered generic. Also contrary to Applicants 11-18-04

Art Unit: 3761

remarks claims 43 and 44 do not read on the elected invention and species because claim 43 is cancelled and claim 44 has been marked as withdrawn and relates to the product made by the process using a piezojet, i.e. the unelected species.

Specification

Priority

4. The benefit claim added by amendment on 4-12-04 is noted. With respect to Applicant's remarks, Applicant refers to the application data sheet filed 11-16-04. While a benefit claim was noted in the transmittal letter of 11-16-01, no ADS of such date is of record in the file.

Drawings

5. The drawings were received on 8-18-03. These drawings are approved by the Examiner.

Claim Objections

6. Claims 45-46 and 52-53 are objected to because of the following informalities: in claims 45 and 46, before "said discrete segments", --the medicinal composition applied in the pattern comprising which forms-- should be inserted and "are applied" should be --is applied--. In claim 52, lines 1-2, "the...a body" should be deleted and on line 3, after "medicament", --composition-- should be inserted. In Claim 53, line 2, before "surface", --the-- should be inserted. Appropriate correction is required.

Claim Language Interpretation

7. With regard to claim 17, see page 4, lines 15-18 and page 5, lines 9-24 of the specification. "Medicaments" is interpreted in light of page 4, line 32- page 5, line 1, page 6, lines 24-28, and page 10, line 17-page 12, line 32. "Porous" is defined as set forth on page 6, line 34-page 7, line 2. "Effective amount" is defined as set forth on page 6, lines 13-17. "A pattern of a matrix of discrete segments" is interpreted in light of page 6, line 23-page 14, line 26 and page 16, line 24-page 17, line 6.

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 14-16, 18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayford '998.

With regard to claims 14, 15, 21 and 22, see claim interpretation section supra, the Figures, col. 1, lines 4-6, col. 3, lines 69 et seq, col. 4, lines 10-26, i.e. the topsheet is 2, the absorbent material is 1, the backsheet is 5, an effective amount is disclosed at col. 2, lines 64 et seq, a medicinal composition is 3, 4 and 6 or just 3 and 4 and disclosed at col. 2, lines 39-60, the discrete segments are 4, a pattern is disclosed at col. 4, lines 30-36, i.e. "a portion of", Figure 1 and 4, i.e. an array, and col. 2, lines 26-29, i.e. clusters, the volume is disclosed at col. 2, lines 17-25(the volume of a sphere is $\frac{4}{3}\pi(r^3)$), i.e. 3 picoliters to 400 nanoliters is equal to .000003-4 cubed mm and a capsule having a diameter of 200 microns has a volume of about .004 cubed mm.

Art Unit: 3761

With regard to claim 16, see Figure 1, the spheres 4 stick out of matrix 6 and the portions sticking out are “substantially” semi-spherical in cross section, see also col. 2, line 18.

With regard to claim 18, see again col. 4, lines 30-36, i.e. “a portion of” and col. 2, lines 26-29, i.e. clusters.

With regard to claim 20, the composition is claimed as including a filler. However, the specifics of the filler have not been disclosed. Therefore, the composition as disclosed at col. 2, lines 39-60 is considered to include such a “filler”.

102/103 Rejections

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 17, 45-46 and 52-53 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hayford ‘998.

Claim 17 claims the frequency of positioning. See page 4, lines 15-18 and page 5, lines 9-24 of the specification. It is especially noted that as disclosed this is just the number of times an applicator “may” fire. Therefore this claim appears to be a product by process claim, i.e. the claiming of the frequency of possible firing of an applicator during the manufacture of the claimed product. This process does not appear to provide any further structure of the article than that already claimed. As set forth in MPEP 2113, it is the structure of the end product of the process which determines patentability not the process. Therefore, the Hayford device includes the same structure or obviously includes the same structure, as best understood.

Art Unit: 3761

Claims 45-46, as best understood, claim the viscosity of application to the topsheet. Therefore these claims appear to be product by process claims, i.e. the claiming of the viscosity during the manufacture of the claimed product. This process does not appear to provide any further structure of the article or end product other than that already claimed, i.e. the viscosity of the discrete segments in the end product is not claimed. As set forth in MPEP 2113, it is the structure of the end product of the process which determines patentability not the process. Therefore, the Hayford device includes the same structure or obviously includes the same structure, as best understood.

Claims 52-53, as best understood, claim a medicament which is applied to the topsheet in a pattern which comprises the discrete segments is melted and then is allowed to cool and solidify. Therefore these claims appear to be product by process claims, i.e. the claiming of the state of a precursor material during the manufacture of the claimed product. This process does not appear to provide any further structure of the article or end product other than that already claimed, i.e. the specific temperature and solidity of the discrete segments in the end product are not claimed. As set forth in MPEP 2113, it is the structure of the end product of the process which determines patentability not the process. Therefore, the Hayford device includes the same structure or obviously includes the same structure, as best understood, see, e.g., col. 5, lines 8-33.

Claim Rejections - 35 USC § 103

12. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayford '998 in view of Vega '209 and Krzysik PCT '500.

Art Unit: 3761

Applicant claims the discrete segments located in a specific pattern not taught by Hayford only discloses application to a portion, e.g. clusters, an array, or the entire surface. However see Vega '209 at col. 29, lines 7-8 and col. 31, lines 19-32 and Krzysik at page 20, lines 19-29, i.e. interchangeability of a portion or the entire surface for the specific pattern as claimed. Therefore, to make the surface portion including segments 4 of Hayford the claimed specific pattern instead would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by Vega and Krzysik.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 14 –18, 20-22, 45-46 and 52-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-17 and 20-23 of copending Application No. 09/990,686(2003/0106605). Although the conflicting claims are not identical, they are not patentably distinct from each other because since the instant application has an effective filing date earlier than '686 but there was no administrative delay

Art Unit: 3761

and Applicants could have avoided separate filings, the one way or In re Vogel test applies, i.e.

are the claims of the instant application obvious in view of the claims of the '686 application.

The answer is yes. With regard to claims 14-16, 18 and 21-22, see claims 12-17 and 20-23 of the

'686 application, as now amended and as best understood, and the definitions therein, e.g. what

is considered a chemistry. Such claims teach substrates which are porous, chemistries, i.e.

medicaments, chemistries which are discrete segments and provide skin separation, i.e. the

substrate on which the chemistries are situated is a "topsheet", and an article which is absorbent

and a diaper. While the absorbent material, backsheet, the position of the sheets and "an

effective amount" are not explicitly claimed, it is well known in the absorbent article art that

absorbent articles like diapers include a topsheet and a backsheet with an absorbent layer

therebetween. Furthermore, it is well known to provide medicaments in amounts which provide

the desired effect, i.e. the "effective amount". Thus to employ the layers and position them as

claimed as well as an effective amount of the medicament chemistry on the device of the '686

claims would be obvious to one of ordinary skill in the art in view of the recognition that the

layers and positioning thereof are well known in diapers and the desire of the '686 claims to

include a diaper and obvious in view of the recognition that a certain amount of the chemistry is

require to be effective and the desire of the '686 claims to provide an effect with the chemistry.

With regard to the limitations of the instant claims which are now broader than those claimed by

the '686 claims, e.g. the volume, once an applicant has received a patent for a species on a more

specific embodiment which would be the case if the '686 issued, he(she) is not entitled to a

patent for the generic or broader invention. This is because the more specific anticipates the

Art Unit: 3761

broader. See *In re Goodman*, supra. With regard to claims 17, 20, 45-46 and 52-53, see discussion supra in paragraphs 9 and 11, which rationales are repeated here.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claim 19 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-17 and 20-23 of copending Application No. 09/990, 686(2003/01066605) in view of Vega '209 and Krzysik '500. See discussion in paragraph 12 supra and claim 18 of '686. Also note col. 30, lines 40-41 of Vega. Therefore to make the selective application, i.e. a portion, of the '686 claims the specific claimed pattern instead would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by Vega and Krzysik.

This is a provisional obviousness-type double patenting rejection.

Common Ownership

16. Claims 14-22, 45-46 and 52-53 directed to an invention not patentably distinct from claims 12-17 and 20-23 of commonly assigned 09/990,686(2003/01066605). Specifically, see the double patenting rejections supra.

17. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/990,686(2003/01066605), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned

Art Unit: 3761

at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

18. The statement of common ownership filed 4-12-04 has been noted but is insufficient to remove the issue of common ownership as it does not identify which invention is referred to by "at the time of the invention" and as set forth in MPEP 706.02(I)(2)(II) it must be shown that the ownership ^{was} at the time the later invention was made.

mm
2-1-05

Response to Arguments

19. Applicants remarks with regard to the informalities in the 4-12-04 response have been noted but are either deemed moot in that the issue has not been reraised or are deemed not persuasive for the reasons set forth supra. Applicant's remarks with regard to the provisional double patenting rejection have been noted. Applicant's remarks with regard to the prior art rejections have been considered but are deemed not persuasive in that such remarks are narrower than the claim language and the teachings of the prior art which does not distinguish the discrete

Art Unit: 3761

segments of the end product from the capsules of Hayford. The claims are directed to an article not a method of manufacture.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any new grounds of rejection were necessitated by the addition of claims 44-77 and the amendments to the claims of '686.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

Art Unit: 3761

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Karin M. Reichle
Primary Examiner
Art Unit 3761

KMR
February 1, 2005